

PRESCRIPTION DRUG AFFORDABILITY BOARD MEETING
Monday, July 24, 2022
Minutes

AGENDA ITEM 1

Call the Meeting to Order

Chair Van Mitchell called the meeting to order at 2:01 p.m.

Board Members present: Van Mitchell, Gerard Anderson, Ph.D., Eberechukwu Onukwugha, MS, Ph.D., Joseph Levy, Ph.D.

AGENDA ITEM 2

Approval of minutes

Chair Mitchell asked for a motion to approve the May 22, 2023 meeting minutes as submitted. Dr. Anderson made the motion, which Dr. Onukwugha seconded, and the Board unanimously approved the minutes.

Action: Minutes APPROVED

AGENDA ITEM 3

Opportunity for Public Comment

No persons registered for an opportunity to provide public comment.

AGENDA ITEM 4

Regulations-chapters COMAR 14.01.01 and COMAR 14.01.04

a. Staff Presentation on Comments and Recommendations

Executive Director York provided an overview of the two sets of proposed regulations COMAR 14.01.01.-05 (General Provisions Chapter) and COMAR 14.01.04.01-05 (Cost Review Chapter), the comments received, revisions to the draft regulations, and an overview of the process. The presentation is available on the Board's website.

Dr. York explained that there have been two comment periods and summarized the comments received by the Board. Dr. York also provided a summary of the revisions proposed to the most recent draft regulations based on the comments received. In addition, Dr. York provided an overview of the cost review selection and study process highlighting opportunities for public comment throughout the process.

b. COMAR 14.01.01.-05 General Provisions Chapter

i. Motion to Approve Draft Regulations

Chair Mitchell asked for a motion to approve draft regulations COMAR 14.01.01.01-05 General Provisions Chapter, as submitted. Dr. Anderson made the motion which Dr.

Onukwuga seconded. Chair Michell then entertained discussion on the motion. There was no discussion.

ii. Vote on Motion

With no opposition, the Board unanimously approved COMAR 14.01.01.01-.05 General Provisions Chapter Fee as submitted.

Action: COMAR 14.01.01.01-.05 General Provisions Chapter APPROVED as submitted.

c. COMAR 14.01.04.01-.05 - Cost Review Chapter

i. Motion to Approve Draft Regulations

Chair Mitchell asked for a motion to approve draft regulations COMAR 14.01.04.01-.05 Cost Review Chapter, as submitted, subject to grammatical and formatting corrections/revisions made by staff. Dr. Anderson made the motion, which Dr. Onukwuga seconded. Chair Michell then entertained discussion on the motion.

Amendments:

- Dr. Anderson proposed an amendment to COMAR 14.01.04.04 section (6), at page 10 of the draft. That section currently reads:

“Within 60 days of the date the request for information is posted to the website or transmitted to the entity, an entity may submit the information requested by the Board, and any other relevant information, in accordance with §C of this regulation.”

- Dr. Anderson proposed that the 60 days be struck and replaced with 30 days, and that sections (7) and (8) be added to read as follows:
 - (7) An entity may request one 30-day extension of time to submit information under §A(6) of this regulation; and
 - (8) A entity shall submit the request for a 30-day extension to the Board in writing on or before the expiration of the initial submission period.

Chair Mitchell asked for a motion to approve the amendment. Dr. Levy made the motion which Dr. Onukwuga seconded.

Dr. Levy asked if there was currently an extension period, and staff clarified that there was not. Under the amendment the total number of days to submit data remains the same (60), but the initial deadline is 30 days, and an entity must request the additional 30 days.

The Board voted unanimously to amend COMAR 14.01.04.01-05. There were no other proposed amendments.

Chair Mitchell reiterated that grammatical changes and technical corrections are permitted.

ii. Vote on Motion

Chair Mitchell entertained a motion to approve COMAR 14.01.04.01-.05 Cost Review Chapter, as amended. Dr. Anderson made the motion, which Dr. Onukwugha seconded. With no opposition, the Board unanimously approved COMAR 14.01.04.01-.05 Cost Review Chapter, as amended.

ACTION: COMAR 14.01.04.01-.05 Cost Review Chapter APPROVED as amended.

AGENDA ITEM 5

Presentation on Upper Payment Action Plan

Continuing the discussion from the May 22, 2023 meeting and PORTAL's instructive program framing upper payment limits (UPLs), Dr. York provided an overview of Maryland's statutory scheme governing UPLs, and identified key decision points in developing the UPL Action Plan. These include decisions such as when should UPLs apply, what drugs do we select for a UPL, how is a UPL determined including various frameworks informing that determination, how is the UPL applied, as well as identifying the next steps in developing a plan. The presentation is available on the Board's website. Several Board members commented on various aspects of the presentation and content.

AGENDA ITEM 6

Administrative Update

- Executive Director York gave an update on the vacant PDAB position. PDAB is looking for qualified candidates with a data background.

AGENDA ITEM 7

Chair's Update

- Chair Mitchell referenced a letter to the Board from AARP.
- Dr. Onukwugha and Dr. Anderson have been reappointed to the Board.
- There will be a special PDAB Board meeting on September 13, 2023 at 9:00am to take final action on pending regulations. This is a week prior to the regularly scheduled September 18, 2023 Board Meeting.
- It has not yet been determined whether the Board will be meeting in person in September.

AGENDA ITEM 8

Adjournment

Chair Mitchell asked for a motion to adjourn. Dr. Anderson made the motion which Dr. Levy seconded. The meeting was adjourned at 3:24 PM.